LEAVE TO FILE
GRANTED AUGUST 26, 2008

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA ex rel. WILLIAM ST. JOHN LACORTE **Plaintiff,** **v.** **WYETH,** **Defendant.**	**Civil Action No. 06-11724-DPW** **FILED IN CAMERA UNDER SEAL**

FIRST SUPPLEMENTAL AND AMENDED CONSOLIDATED COMPLAINT

NOW INTO COURT, through undersigned counsel, comes Relator, William St. John LaCorte, by, on behalf of, and in the name of the United States of America, its departments and agencies, including but not limited to the Department of Health & Human Services (hereinafter sometimes referred to as "DHHS"), the State of California, the State of Delaware, the District of Columbia, the State of Florida, the State of Hawaii, the State of Illinois, the State of Indiana, the State of Louisiana, the Commonwealth of Massachusetts, the State of Michigan, the State of Montana, the State of Nevada, the State of New Hampshire, the State of New Mexico, the State of New York, the State of Tennessee, the State of Texas, the Commonwealth of Virginia, and the State

of Wisconsin (hereinafter sometimes referred to collectively as the "Relator States"), who respectfully files this First Supplemental and Amended Consolidated Complaint in the above-captioned matter against Wyeth, formerly known as American Home Products (hereinafter referred to as "Wyeth"), defendant herein, through its agents, employees, and subsidiaries, for money damages, civil penalties, and all other recoveries allowed, arising out of defendant's violations of the Federal False Claims Act, 31 U.S.C. § 3729, *et seq.*, currently pending under Seal pursuant to 31 U.S.C. § 3729, *et seq.*, as well as arising from violations of the California False Claims Act, Cal. Gov't Code §§12650, *et seq.*; the District of Columbia False Claims Act, D.C. Code Ann. §§2-308.03, *et seq.*; the Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, §§1201, *et seq.*; the Florida False Claims Act, Fla. Stat. §§68.081, *et seq.*; the Hawaii False Claims Act, Haw. Rev. Stat. §§661-21, *et seq.*; the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. Ann. §§175/1, *et seq.*; the Indiana False Claims and Whistleblower Protection Act, Indiana Code §5-11-5.5; the State of Louisiana's Medical Assistance Programs Integrity Law, La. R.S. 46:437.1, *et seq.*; the Massachusetts False Claims Act, Mass. Ann. Laws. Ch. 12, §§5A, *et seq.*; the Michigan Medicaid False Claims Act, MCLS §§400.601, *et seq.*; the Montana False Claims Act, Mont. Code Anno. §§17-8-401, *et seq.*; Nevada Submission of False Claims to State or Local Government, Nev. Rev. Stat. §§357.010, *et seq.*; the New Hampshire False Claims Act, RSA tit. XII, Ch. 167: 61-b; the New Mexico False Claims Act, N.M. Stat. Ann. §§27-14-1, *et seq.*; the New York False Claims Act, NY CLS St. Fin. §§187, *et seq.*; the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§71-5-171, *et seq.*; the Texas False Claims Act, Tex. Hum. Res. Code §§36.001, *et seq.*;

the Virginia Fraud Against Taxpayers Act, Va. Code §§8.01-216.1, *et seq.*; and the Wisconsin False Claims for Medical Assistance Act, Wis. Stats. §§20.931 (hereinafter sometimes referred to collectively as the "State False Claims Acts"), as well as violations of other state and federal laws, which violations are described hereinafter with particularity, as follows:

I. INTRODUCTION AND SUMMARY OF THE ALLEGATIONS

This action was filed pursuant to the False Claims Act against Wyeth, formerly known as American Home Products, a United States conglomerate with a Pharmaceutical Products division. This action has been filed by Dr. William St. John LaCorte, relator, on behalf of the United States of America and various States, as set forth infra, to recover damages and penalties resulting from Wyeth's fraudulent and illegal practices designed to increase its market share. These fraudulent and illegal practices involve programs that Wyeth instituted nationwide to induce hospitals to prescribe Protonix, a Wyeth product, over its competitors' products, and to switch patients from their prescribed medications to Protonix, by virtue of steep discounts and other monetary incentives, in violation of federal and state laws, including but not limited to anti-kickback laws, "best price" requirements, the Food, Drug, and Cosmetic Act, and the Prescription Drug Marketing Act, as described infra.

Wyeth manufactures and markets the drug pantoprazole sodium under the brand name Protonix. Pantoprazole sodium is a compound that inhibits gastric acid secretion and is metabolized extensively in the liver. Pantoprazole is a Proton Pump Inhibitor (hereinafter sometimes referred to as a "PPI") that suppresses the final step in gastric acid production.

On February 2, 2000, the Food and Drug Administration (hereinafter sometimes referred to as the "FDA") approved Protonix delayed release tablets for the short-term treatment of erosive esophagitis associated with gastroesophageal reflux disease (GERD), which is an extremely rare condition. Later, on June 12, 2001, Protonix delayed release tablets received an additional indication for maintenance of healing of erosive esophagitis. On April 19, 2002, Protonix delayed release tablets received its third indication, which is for pathological hypersecretory conditions including Zollinger-Ellison Syndrome. On the other hand, I.V. Protonix was approved on March 22, 2001 "for short-term treatment (7 to 10 days) of gastroesophageal reflux disease (GERD), as an alternative to oral therapy in patients who are unable to take Protonix (pantoprazole sodium) delayed-release tablets. Safety and efficacy of Protonix I.V. for injection as an initial treatment for GERD have not been demonstrated." FDA letter of approval, dated March 22, 2001. On October 19, 2001, the FDA approved the use of Protonix I.V. for injection in the treatment of pathological hypersecretion associated with Zollinger-Ellison Syndrome. Protonix is sold as a delayed-release tablet and as an intravenous solution. There is no generic equivalent to the tablet, and, at the time it received FDA approval, the I.V. version was the sole FDA-approved PPI in I.V. form.

Wyeth devised multiple schemes to increase Protonix's market share among PPI's. One of the schemes that Wyeth instituted, beginning in early 2001 and continuing through mid-2007, was a nominal pricing scheme providing steep discounts to hospitals to either start patients on Protonix, or switch them to Protonix from other PPI's during their hospitalization, with the goal of the patients continuing on Protonix after their dischage and, thus, achieving a spillover effect and "pull-through"

strategy. Therefore, Wyeth's scheme was to offer economic inducements to hospitals to place Protonix as a preferred drug on the formulary and induce hospital pharmacies to make a therapeutic interchange/automatic substitution from other prescribed drugs in the PPI class to the chemically different drug, Protonix. The scheme included substituting Protonix for other PPI's that treat conditions for which Protonix was not indicated. Thus, Protonix was being substituted on patients for non-indicated–and, thus, not FDA approved–uses (off-label use).

Additionally, Wyeth's schemes employed a contractual agreement known as the Protonix Performance Agreement (hereinafter sometimes referred to as the "Performance Agreement"). The Performance Agreement tied the percentage of hospital PPI market share for Protonix to a substantial economic discount or rebate on both the tablet and the I.V. product (respectively, 94 percent and 80 percent). Consequently, the program reduced the per pill price of Protonix from the current market price of $2.70-$3.00, to as low as $0.16 per pill. The I.V. version retails for approximately $25.00 per dose, but, under the program, discounts to $4.00. Moreover, Wyeth's schemes included a bundling scheme, whereby a hospital could receive the discount only by: (1) purchasing both the tablet and I.V. product, and (2) achieving Wyeth's required market share in violation of the Protonix Approval Agreement with the FDA. Wyeth conditioned the hospital's purchase of the deeply discounted I.V. on the purchase of the Protonix tablets by being placed as the preferred PPI on the formulary in order to increase its market share, such that it exceeded its FDA-approved indications. The resulting price concessions were greater than those that would have been available had the bundled Protonix I.V. and tablets been purchased separately or outside of the bundled arrangement.

Wyeth was required to allocate discounts proportionately to the dollar value of the units of each drug sold under a bundled arrangement, pursuant to the Medicaid Rebate Act in determining "best price."[1] The aggregate value of the discounts was required to be proportionately allocated across all the drugs in the bundle. Defendant, Wyeth, failed to proportionately allocate across all the drugs in the bundle the aggregate value of the discounts. This should have been reported to the federal government as a new best price for the tablets. Unfortunately, the Medicaid Program and other federal health programs were being charged in excess of $3.00 per tablet, while the hospitals and other related health care institutions were receiving the tablets for as low as $.16 per tablet.

Under the Medicaid Rebate Act, 42 U.S.C. § 1396r-8, Wyeth was required to report these discounts as the best price in order to accurately calculate the rebates to which the States were entitled. Yet, Wyeth knowingly concealed these discounted prices, because the true discounted prices, if reported, would have required Wyeth to provide much greater rebates to the States.

Wyeth knowingly violated the Federal False Claims Act by knowingly presenting or causing to be presented to the Secretary of the Department of Health and Human Services (DHHS) false and/or fraudulent quarterly calculations of the Protonix best price, which were needed for the Secretary to accurately determine the Rebate Payment to each State Medicaid Agency for Wyeth's Protonix Covered Outpatient Drug paid for by the State Medicaid Agency during the corresponding quarter. As a result, Wyeth received approval and/or payment based on their false and/or fraudulent best price.

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[1] 42 U.S.C. § 1396r-8

Table 1, set forth in paragraph 11, infra, reflects that pursuant to the National Protonix Utilization Payments by Medicaid, according to the Medicaid Utilization Data published by Centers for Medicare & Medicaid Services (hereinafter sometimes referred to as "CMS"), the average Medicaid payment per Protonix tablet was $2.75 in 2000, $2.75 in 2001, $2.98 in 2002, $3.37 in 2003, $3.35 in 2004, $3.81 in 2005, $3.57 in 2006, and $3.81 in 2007. However, the Medicaid Program should have been charged the best price, $.16 per tablet, as $.16 was the best price offered by Wyeth to for-profit hospitals and private purchasers nationwide, since the Medicaid Rebate Program was intended to provide the State Medicaid Programs the benefit of the best price for which the manufacturer sold the drug to any private purchaser. H.R. Rep. 101.881 at 96 (1990).

Additionally, these schemes directly impacted patient safety by providing a kick-back that induced hospitals to avoid or alter the treating physician's professional judgment, as well as by inducing the use of Protonix instead of PPI's and other classes of drugs proven safe and effective for the specific conditions of hospital patients in susceptible patient populations, unlike Protonix, which has not been proven safe and effective for uses that are not FDA approved.

Wyeth's economic motive in implementing the schemes was to achieve an increased market share, as well as to permanently capture those patients switched to the more expensive Protonix for the more lucrative and long-term outpatient drug sales by achieving a spillover effect arising from the patients' continued use of oral Protonix after their discharge from the hospital. Table 1, set forth in paragraph 11, reflect meteoric rise in Protonix use by Medicaid beneficiaries from 2000 through 2005, until the implementation of Medicare Part D in early 2006, which resulted in the automatic

transfer of eligible Medicaid beneficiaries to Medicare Part D for prescription drug benefits.

Wyeth's violations of the Federal and State False Claims Acts through the above-referenced schemes include but are not limited to the following: (1) Knowingly creating an illegal prescription for which state and/or federal reimbursement is prohibited; (2) Knowingly providing illegal remuneration in the form of an economic kick-back for promotion of drug selection and dosage; (3) Knowingly promoting off-label drug use (non-indicated uses) in violation of the Food, Drug, and Cosmetic Act and the Prescription Drug Marketing Act; (4) Knowingly breaching federal "best price" requirements by hiding rebates and discounts given upon achieving the market share requirements of the program; (5) Knowingly creating an illegal price reporting scheme through its tying-bundling arrangement between the tablet and the I.V. version of Protonix by requiring the purchase of both the tablet and I.V. forms in order to receive the deep discount; and in failing to proportionately allocate the aggregate value of the discounts across all the drugs in the bundle, resulting in a false and fraudulent best price. Wyeth knowingly presented said false and fraudulent best price claims to employees and officers of the United States Government for payment or approval, thus violating the False Claims Act. 31 U.S.C. §3729(a)(1).

In connection with the filing of the original Complaint, relator provided the United States government with thousands of pages of documents evidencing and supporting Wyeth's fraudulent and illegal practices described herein. Relator has also provided additional information regarding Wyeth's fraudulent and illegal practices to the government both prior to and since the filing of the Complaint.

In summary, ***Diagram I***, attached hereto and made a part hereof, demonstrates how the contractual relationship between Wyeth and the hospitals corrupted the hospitals' administrative process and prescription process at multiple levels, and corrupted the independent decision-making of physicians at hospitals, including the hospital committees, and specifically, the Pharmacy and Therapeutics Committee (hereinafter sometimes referred to as the "P&T Committee").

Diagram II, attached hereto and made a part hereof, demonstrates how Wyeth used rebates and educational grants to influence hospitals' prescription process and the independent decision-making of physicians at hospitals, as well as to advance off-label utilization of their drug, Protonix.

Diagram III, attached hereto and made a part hereof, demonstrates the flow of the drugs and money between the hospital organization and Wyeth.

II. PARTIES

A. Plaintiffs

1. Plaintiff, the United States of America, by and through its department, DHHS, particularly, the Centers for Medicare & Medicaid Services ("CMS"), within DHHS, has the responsibility to administer federal health programs, including but not limited to Medicare, Medicaid, Champus, Indian Health Services, and GHEA.

2. The Medicare Program is a federally-funded health insurance program, funded by taxpayers, which provides certain health care benefits to particular individuals, including those persons over age 65, disabled individuals, and those suffering from end-stage renal disease. Medicare was created in 1965 in Title XVIII of the Social Security Act. Medicare has three parts:

Part A, the Basic Plan of Hospital Insurance, which covers the cost of hospital services and related ancillary services such as home health care agencies (hereinafter sometimes referred to as "HHA's") and skilled nursing facilities (hereinafter sometimes referred to as "SNF's"); Part B, which covers the cost of physicians' services and other ancillary services not covered by Part A; and Part D, which is a prescription drug benefit that pays for outpatient prescription drugs for Medicare beneficiaries. Medicare Part D has been in effect since January 1, 2006, and includes substantial premium and cost-sharing assistance for beneficiaries with low incomes and modest assets. Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395, *et seq*. On January 30, 2007, Medicare Part D was providing outpatient prescription drug benefits to 24 million individuals.

3. Medicare Part D, like Medicaid, discussed infra, only covers the cost of FDA approved prescription drugs used for "a medically accepted indication." 41 U.S.C. §§ 1395w-102(e)9(1), 1395w-151(a)(2). A "medically accepted indication" is any use or indication that is FDA approved or supported by one or more citations in specified drug compendia. 42 U.S.C. § 1396r-8(k)(6). Therefore, Medicare Part D will not cover drugs that are not to be used for a medically accepted condition, and will not cover drugs that are not FDA approved.

4. Medicare Part D has covered outpatient Protonix Oral since January 1, 2006.

5. Beginning on January 1, 2006, beneficiaries who were eligible for both Medicare Part D and Medicaid drug coverage ("dual eligibles") were automatically qualified and, thus, were automatically enrolled into Medicare Part D.

6. Private prescription drug plans (PDP's) and Medicare prescription drug plans (MA-

PD's) both offer the Medicare Part D outpatient prescription drug benefit. Many different plans are available for Medicare beneficiaries to choose from, with Medicare reimbursing said private plans. Wyeth, through its continued schemes, inducements, kickbacks, and illegal off-label practices, knowingly presented, or caused to be presented, to an officer or employee of the United States Government false or fraudulent claims for payment or approval to Medicare Part D, thus violating the Federal False Claims Act. 31 U.S.C. §3729(a)(1).

7. At all times relevant to this action, Medicare Part A and Part B covered Protonix I.V. for both inpatient and outpatient Medicare beneficiaries. When inpatient beneficiaries have been given Protonix I.V. in hospitals, said hospitals have been reimbursed for any drugs administered, based upon the nature of the illness being treated. Additionally, since January 1, 2005, Medicare has reimbursed providers a percentage of outpatient Protonix I.V.'s "average sales price." Prior to January 1, 2005, Medicare reimbursed providers a percentage of Protonix I.V."s "average wholesale price."

8. Similarly, Medicare reimbursed inpatient Protonix Oral for Medicare beneficiaries, based upon the nature of the illness being treated. Through December 31, 2005, Medicare generally did not reimburse providers for outpatient Protonix Oral to Medicare beneficiaries, with certain exceptions, including some patients in nursing home facilities.

9. The Medicaid Program is a jointly funded, federal-state health insurance program, funded by taxpayers, which provides certain health care benefits to those who are indigent and unable to afford health care benefits. The primary purpose of the Medicaid Program is to enable

each state, as far as practicable under the circumstances in such state, to furnish medical assistance on behalf of families with dependent children and of aged, blind, or disabled individuals whose income and resources are insufficient to meet the costs of necessary medical services. 42 U.S.C. §§ 1396-1396v. The Medicaid Program was created in 1965 in Title XIX of the Social Security Act. Funding for Medicaid is shared between the federal government and those states participating in the program, collectively referred to as "Medicaid Funds." The funding apportionment varies from state to state, with the federal contribution calculated separately for each state, but usually approximates an equal division. 42 U.S.C. §§ 1396b; 1396d(b).

10. Medicaid covers approximately 47 million individuals, including children, the aged, blind, and/or disabled, and individuals who are eligible to receive federally assisted income maintenance payments.

11. From 2000 through 2007, Table I, as follows, reflects the National Protonix Tablets Outpatient Utilization Payments Reimbursements by Medicaid, according to the Medicaid Utilization Data, as published by CMS:

Table 1

Totals	Total Reimbursement Amt. - Tablets	Total Tablets Reimbursed	Average Reimbursement per Tablet	No. Of Prescriptions
2000	$ 8,528,038.68	3,105,315	$ 2.75	99,815
2001	$ 72,394,014.14	26,347,338	$ 2.75	847,148
2002	$205,625,970.27	69,068,265	$ 2.98	2,200,018
2003	$398,868,474.61	118,490,683	$ 3.37	3,649,739
2004	$586,067,338.94	174,858,998	$ 3.35	5,393,309
2005	$440,406,258.37	115,479,801	$ 3.81	4,218,729
2006	$ 76,568,932.74	21,453,334	$ 3.57	651,082
2007	$ 42,903,865.63	11,275,184	$ 3.81	350,893

12. Each state is allowed, within certain parameters, to design its own medical assistance plan, subject to approval by the Department of Health and Human Services (DHHS). In addition to other forms of medical assistance, states may also cover prescription drugs under the Medicaid Program. 42 U.S.C. § 1396(d)(a)(12). Drugs purchased by Medicaid recipients account for roughly 10 percent of all prescription drugs purchased in the United States.

13. The following states, as set forth below, are also named as plaintiffs, and their respective state false claims acts included, pursuant to the Court's pendent jurisdiction under 31 U.S.C. § 3732.

14. Plaintiff, the State of California (hereinafter sometimes referred to as "California"), provides Medicaid benefits under its Medi-Cal Program. During the relevant time periods set forth herein, Wyeth's Protonix Oral and I.V. drugs were provided to Medicaid recipients in California and were a covered Medicaid benefit under California's Med-Cal Program.

15. Plaintiff, the State of Delaware (hereinafter sometimes referred to as "Delaware"), provides Medicaid benefits under its Medicaid Program. During the relevant time periods set forth herein, Wyeth's Protonix Oral and I.V. drugs were provided to Medicaid recipients in Delaware and were a covered Medicaid benefit under Delaware's Medicaid Program.

16. Plaintiff, the District of Columbia, provides Medicaid benefits under its Medicaid Program. During the relevant time periods set forth herein, Wyeth's Protonix Oral and I.V. drugs were provided to Medicaid recipients in the District of Columbia and were a covered Medicaid

benefit under the District of Columbia's Medicaid Program.

17. Plaintiff, the State of Florida (hereinafter sometimes referred to as "Florida"), provides Medicaid benefits under its Medicaid Program. During the relevant time periods set forth herein, Wyeth's Protonix Oral and I.V. drugs were provided to Medicaid recipients in Florida and were a covered Medicaid benefit under Florida's Medicaid Program.

18. Plaintiff, the State of Hawaii (hereinafter sometimes referred to as "Hawaii"), provides Medicaid benefits under its Medicaid Program. During the relevant time periods set forth herein, Wyeth's Protonix Oral and I.V. drugs were provided to Medicaid recipients in Hawaii and were a covered Medicaid benefit under Hawaii's Medicaid Program.

19. Plaintiff, the State of Illinois (hereinafter sometimes referred to as "Illinois"), provides Medicaid benefits under its Medicaid Program. During the relevant time periods set forth herein, Wyeth's Protonix Oral and I.V. drugs were provided to Medicaid recipients in Illinois and were a covered Medicaid benefit under Illinois' Medicaid Program.

20. Plaintiff, the State of Indiana (hereinafter sometimes referred to as "Indiana"), provides Medicaid benefits under its Medicaid Program. During the relevant time periods set forth herein, Wyeth's Protonix Oral and I.V. drugs were provided to Medicaid recipients in Indiana and were a covered Medicaid benefit under Indiana's Medicaid Program.

21. Plaintiff, the State of Louisiana (hereinafter sometimes referred to as "Louisiana"), provides Medicaid benefits under its Medicaid Program. During the relevant time periods set forth herein, Wyeth's Protonix Oral and I.V. drugs were provided to Medicaid recipients in Louisiana and

were a covered Medicaid benefit under Louisiana's Medicaid Program.

22. Plaintiff, the Commonwealth of Massachusetts (hereinafter sometimes referred to as "Massachusetts"), provides Medicaid benefits under its Medicaid Program. During the relevant time periods set forth herein, Wyeth's Protonix Oral and I.V. drugs were provided to Medicaid recipients in Massachusetts and were a covered Medicaid benefit under Massachusetts' Medicaid Program.

23. Plaintiff, the State of Michigan (hereinafter sometimes referred to as "Michigan"), provides Medicaid benefits under its Medicaid Program. During the relevant time periods set forth herein, Wyeth's Protonix Oral and I.V. drugs were provided to Medicaid recipients in Michigan and were a covered Medicaid benefit under Michigan's Medicaid Program.

24. Plaintiff, the State of Montana (hereinafter sometimes referred to as "Montana"), provides Medicaid benefits under its Medicaid Program. During the relevant time periods set forth herein, Wyeth's Protonix Oral and I.V. drugs were provided to Medicaid recipients in Montana and were a covered Medicaid benefit under Montana's Medicaid Program.

25. Plaintiff, the State of Nevada (hereinafter sometimes referred to as "Nevada"), provides Medicaid benefits under its Medicaid Program. During the relevant time periods set forth herein, Wyeth's Protonix Oral and I.V. drugs were provided to Medicaid recipients in Nevada and were a covered Medicaid benefit under Nevada's Medicaid Program.

26. Plaintiff, the State of New Hampshire (hereinafter sometimes referred to as "New Hampshire"), provides Medicaid benefits under its Medicaid Program. During the relevant time periods set forth herein, Wyeth's Protonix Oral and I.V. drugs were provided to Medicaid recipients

in New Hampshire and were a covered Medicaid benefit under New Hampshire's Medicaid Program.

27. Plaintiff, the State of New Mexico (hereinafter sometimes referred to as "New Mexico"), provides Medicaid benefits under its Medicaid Program. During the relevant time periods set forth herein, Wyeth's Protonix Oral and I.V. drugs were provided to Medicaid recipients in New Mexico and were a covered Medicaid benefit under New Mexico's Medicaid Program.

28. Plaintiff, the State of New York (hereinafter sometimes referred to as "New York"), provides Medicaid benefits under its Medicaid Program. During the relevant time periods set forth herein, Wyeth's Protonix Oral and I.V. drugs were provided to Medicaid recipients in New York and were a covered Medicaid benefit under New York's Medicaid Program.

29. Plaintiff, the State of Tennessee (hereinafter sometimes referred to as "Tennessee"), provides Medicaid benefits under its Medicaid Program. During the relevant time periods set forth herein, Wyeth's Protonix Oral and I.V. drugs were provided to Medicaid recipients in Tennessee and were a covered Medicaid benefit under Tennessee's Medicaid Program.

30. Plaintiff, the State of Texas (hereinafter sometimes referred to as "Texas"), provides Medicaid benefits under its Medicaid Program. During the relevant time periods set forth herein, Wyeth's Protonix Oral and I.V. drugs were provided to Medicaid recipients in Texas and were a covered Medicaid benefit under Texas' Medicaid Program.

31. Plaintiff, the Commonwealth of Virginia (hereinafter sometimes referred to as "Virginia"), provides Medicaid benefits under its Medicaid Program. During the relevant time periods set forth herein, Wyeth's Protonix Oral and I.V. drugs were provided to Medicaid recipients

in Virginia and were a covered Medicaid benefit under Virginia's Medicaid Program.

32. Plaintiff, the State of Wisconsin (hereinafter sometimes referred to as "Wisconsin"), provides Medicaid benefits under its Medicaid Program. During the relevant time periods set forth herein, Wyeth's Protonix Oral and I.V. drugs were provided to Medicaid recipients in Wisconsin and were a covered Medicaid benefit under Wisconsin's Medicaid Program.

B. Relator

33. Relator, William St. John LaCorte, M.D. (hereinafter sometimes referred to as "Dr. LaCorte") was a citizen of the United States and a resident of the State of Louisiana at the time that he filed the original Complaint in this action.

34. Dr. LaCorte graduated from Johns Hopkins University in 1970, where he received a B.A. Liberal Arts degree. Dr. LaCorte also graduated from Tulane University School of Medicine in 1974, as well as Tulane School of Public Health in 2005, where he received a Master's Degree in Public Health.

35. Dr. LaCorte is a Board Certified Internal Medicine physician, with 30+ years of specialization in Geriatrics. Thus, a large portion of Dr. LaCorte's practice relates to the care of sick elderly patients.

36. Dr. LaCorte admits and treats patients in many hospitals and nursing homes throughout the New Orleans metropolitan area. In his capacity, relator has ordered pharmaceuticals to be administered in connection with the treatment of his patients. In particular, relator has ordered the administration of PPI's and histamine blockers, which prevent the formation of stomach acid and

thereby treat various gastrointestinal diseases.

37. Relator is the original source of relevant information upon which this action is based within the meaning of 31 U.S.C. § 3730(e)(4)(B).

38. Dr. LaCorte is a hospital insider who serves on several hospital committees and primarily treats a vulnerable group of patients, the geriatric population. Over the years, he has uncovered several fraudulent schemes to fleece the public fisc, that range from manipulation of lab orders to therapeutic interchange (also known as automatic substitution), false and fraudulent calculation and reporting of best price, and bundling of pharmaceutical products, offering inducements and kick-backs to hospitals and physicians to manipulate the markets for inpatient and outpatient drugs and promoting off-label indications through various manipulations. Additionally, Dr. LaCorte serves as Medical Director for several nursing homes and served as the Chairman of the Geriatric Committee of the Louisiana State Medical Society. He is an active member of the Louisiana State Medical Society, the American Medical Association, and has served on various hospitals' Pharmacy and Therapeutics Committees (P&T Committees).[2] ***Exhibit 1*** is Dr. LaCorte's CV, attached hereto and make a part hereof.

39. Relevant information was supplied by the relator to the government contemporaneous with the filing of the Complaint for Money Damages and Civil Penalties in this matter. Subsequent to the filing of this action, relator has continued to provide information relevant to this action to the

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[2]The Pharmacy and Therapeutics Committee is a standing committee of the Medical Executive Committee and serves as the official organizational liaison between the medical staff and the Department of Pharmacy Services.

United States government as such information has become known to him, including but not limited to providing the government with thousands of pages of documents.

C. **Defendant**

40. Defendant, Wyeth, formerly known as American Home Products, is a foreign corporation that conducts business within the States of Louisiana and Massachusetts, as well as in the other plaintiff states in this action. Defendant, Wyeth, contracts with local hospitals and other related health care institutions in said states to sell its version of a PPI, namely Protonix.

III. JURISDICTION AND VENUE

41. This is a case brought by the Relator against the defendant under the Federal False Claims Act, 31 U.S.C. §§ 3729, *et seq.*

42. This Court has jurisdiction of this action asserting claims arising under the laws of the United States, pursuant to 28 U.S.C. § 1331.

43. This Court has jurisdiction of this action in which the United States is a plaintiff, pursuant to 28 U.S.C. § 1345.

44. This Court has jurisdiction of the claims asserted in this action under the False Claims Act, 31 U.S.C. §§ 3729-3733.

45. Venue lies in this district under 31 U.S.C. § 3732(a) because the defendant can be found in this district, the defendant transacts business and sells its pharmaceuticals within this district, and one or more acts proscribed by 31 U.S.C. §§ 3729, *et seq.* occurred in this district.

46. Venue lies in this district under 28 U.S.C. § 1391(b) and (c) because the defendant

is a corporation that has one or more agents and places of business in this district and is subject to personal jurisdiction in this district; and a substantial part of the events giving rise to the claims asserted herein occurred in this district.

47. This Court has pendent jurisdiction of this action in which the State of California, State of Delaware, District of Columbia, State of Florida, State of Hawaii, State of Illinois, State of Indiana, State of Louisiana, Commonwealth of Massachusetts, State of Michigan, State of Montana, State of Nevada, State of New Hampshire, State of New Mexico, State of New York, State of Tennessee, State of Texas, Commonwealth of Virginia, and State of Wisconsin are plaintiffs, pursuant to 31 U.S.C. § 3732.

IV. BACKGROUND AND FACTUAL ALLEGATIONS

A. Dr. LaCorte's Experiences with Wyeth's Schemes

48. From in or about the Fall of 2000 through 2006 or later, Wyeth has engaged in the scheme described herein, in violation of the False Claims Act, other federal laws, and various state false claims laws.

49. Wyeth first obtained an FDA indication for oral Protonix in February 2000. That indication was for a very limited GI condition, erosive esophagitis with associated GERD.

50. On Tuesday, September 10, 2002, Dr. LaCorte was given the Protonix Performance Agreement, attached hereto and made a part hereof as ***Exhibit 2***, by Monica Caldarera, area account manager for Wyeth Pharmaceuticals, as evidenced by ***Exhibit 3***, attached hereto and made a part hereof. Hospitals were rewarded with a 94 percent discount on oral Protonix and an 80 percent

discount on I.V. Protonix if they achieved a ≥ 60 percent quarterly Protonix oral market share. This was a violation of the Protonix Approval Agreement between Wyeth and the FDA, which was disclosed to Dr. LaCorte during a meeting in then Congressman David Vitter's office by Dr. Lilia Talarico, Director of the FDA Division of Gastrointestinal and Coagulation Drug Products on March 21, 2001, when Dr. LaCorte met with Dr. Talarico, Congressman Vitter, and Dr. Janet Woodcock, another FDA official. Dr. Talarico specifically indicated to Dr. LaCorte that the FDA, as a condition of approval of the I.V. Protonix, had directed Wyeth that it could not promote the I.V. formulation instead of any other indicated Proton Pump Inhibitors that had been prescribed. In doing so, the FDA in effect recognized that hospitals might be induced to utilize Protonix I.V. over tablet formulations of PPI's because, ultimately, the hospital stood to benefit financially therefrom. Dr. LaCorte's notes of said meeting are attached hereto and made a part hereof as ***Exhibit 4***.

51. On July 28, 2003, Dr. LaCorte presented to the United States Department of Justice in Philadelphia a transcript of the September 10, 2002 conversation that he had with Wyeth representative Monica Caldarera, when she handed him the Protonix Performance Agreement. Said transcript is attached hereto and made a part hereof as ***Exhibit 5.*** This scheme is a classic improper and illegal method for pharmaceutical market entry and control. First, obtain formulary status; second, implement Therapeutic Interchange, which changes the physician's written orders for the accepted Proton Pump Inhibitor with all relevant FDA indications; third, get the doctors used to prescribing I.V. and oral Protonix; and then fourth, eliminate competition from the other established Proton Pump Inhibitors by enforcing the market share requirement in exchange for the discounts.

Although there was no market share requirement needed to get a 94% discount on the oral Protonix, an increasing discount on the I.V. Protonix was tied to increasing market share of oral Protonix, which was in competition with the other oral Proton Pump Inhibitors and H2 blockers. Unlike Protonix, the other oral Proton Pump Inhibitors had obtained the appropriate FDA indications.

52. Wyeth obtained FDA approval more quickly than it would have otherwise by asking the FDA to approve Protonix tablets for only one single short-term indication, and then, through Wyeth's marketing scheme, which was dependent upon bundling the pills with the I.V. Protonix and Therapeutic Interchange/Automatic Substitution[3] of medication. Unfortunately for Wyeth, there were no therapeutic equivalents to its Protonix tablets, as declared by the U.S. Food and Drug Administration. The FDA's Drug Detail page for Protonix tablets is attached hereto and made a part hereof as ***Exhibit 6.***

53. Despite Protonix's lack of therapeutic equivalents to any other Proton Pump Inhibitor, and limited FDA-approved indications, Wyeth obtained a market share that included long-term use for multiple conditions. This far exceeded Protonix's single approved indication. Also, since the appropriate studies to obtain appropriate FDA indications for long-term use were not done, the long-

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[3] "Therapeutic interchange involves the dispensing of chemically different drugs that are considered to be therapeutically equivalent. Therapeutically equivalent drugs are chemically dissimilar but produce essentially the same therapeutic outcome and have similar toxicity profiles. Usually these drugs are within the same pharmacologic class. They frequently differ in chemistry, mechanism of action, and pharmacokinetic properties, and may possess different adverse reaction, toxicity, and drug interaction profiles." (Source: "ACCP Position Statement: Guidelines for Therapetic Interchange," American College of Clinical Pharmacy, *Pharmacotherapy*, 1993;13(3):252-256)

term safety (including potential for increasing the chance of cancer) and efficacy of Protonix tablets and I.V. are unknown.

54. Further, Wyeth marketed their Protonix for off-label use. In hospitals which practice Therapeutic Interchange, the pharmacist produces a computerized list of medications that are part of the patient's chart. Upon discharge, the physician relies upon this list to write his prescriptions for outpatient use. Wyeth knows that the physician will rely upon this Medication Administration Record (MAR) to order the outpatient medications and will fail to notice that a switch from the patient's previous outpatient medications (that the patient had been taking pursuant to a physician's prescription prior to admission to the hospital) has been made.

55. The Protonix Performance Agreement, covering the period 7/1/03 thru 9/30/03, is attached hereto and made a part hereof as ***Exhibit 7***. These agreements tie increasing discounts on I.V. Protonix to increasing Protonix Oral and I.V. market share.

56. Hospitals such as Specialty Hospital were getting a deep discount on both Prevacid and Protonix, paying approximately $.20 a pill (***Exhibit 8***, attached hereto and made a part hereof). Others, who did not exchange market share for discounts, were paying considerably more for Protonix during this period of time (***Exhibits 9-14,*** attached hereto and made a part hereof). Additionally, Omeprazole (generic Prilosec) was available at a considerable savings, and savings were offered to the patients, instead of the hospitals (***Exhibit 15,*** attached hereto and made a part hereof).

57. Although Tenet hospitals automatically switch patients to the relatively expensive

brand Protonix in exchange for a discount on I.V. Protonix according to the Protonix Performance Agreement with Wyeth, the Tenet HMO instructed its doctors to switch them back to generic Prilosec once the patient was discharged. By contrast, Tenet did not instruct physicians to switch all other patients, including Medicaid patients, back to the cost-effective generic Prevacid. ***(Exhibit 16,*** attached hereto and made a part hereof.)

58. Upon information and belief, this practice did not occur only in Louisiana hospitals, but in fact occurred nationwide.

59. On June 2, 1999, IMS HEALTH, self-described as the world's leading provider of information solutions to the pharmaceutical and healthcare industries, was monitoring daily prescriptions based on a sample from the National Prescription Audit Plus (TM) (NPA) pharmacy panel. IMS was able to provide detailed feedback to drug companies to determine the effectiveness of their drug switching programs. "IMS HEALTH's weekly prescription tracking service is the most complete service of its kind covering the U.S. pharmaceutical industry. The service provides comprehensive coverage of three U.S. retail channels-chain drugstores, independent pharmacies and food stores with pharmacies-and includes cash and Medicaid prescriptions as well as third party reimbursement." (***Exhibit 17***, attached hereto and made a part hereof.)

60. On June 22, 2000, Dr. LaCorte received a response to his inquiry to the Louisiana Board of Pharmacy regarding the substitution of prescribed drugs. "In response to your letter of June 20, wherein you requested 'a written response indicating if automatic substitution of Pepcid for Zantac without notifying the attending physician is in compliance with Louisiana State Rules', the

answer is no." (***Exhibit 18***, attached hereto and made a part hereof.)

61. The June 20, 2000 minutes and proposed agenda for the Tuesday July 18, 2000 East Jefferson Pharmacy and Therapeutics Committee are attached hereto and made a part hereof as ***Exhibit 19***. Under formulary management, the section on Proton Pump Inhibitors states: "The hospital is presently using Prevacid as the Proton Pump Inhibitor of choice. By changing to Protonix, the hospital can save approximately $20,000 per year. Only a select five gastroenterologists on staff were polled regarding changing to Protonix and all were agreeable. Dr. Penico requested that all Gastroenterologists on staff be sent a letter requiring a signature indicating approval of this change. Follow Up: Malcolm Schuler will send a letter to all Gastroenterologists on staff." Dr. LaCorte does not know if these signatures were ever obtained.

62. Documents from the August 8, 2000 meeting of the Memorial Medical Center Pharmacy and Therapeutics Committee indicate that when Memorial Medical Center was paying the relatively expensive price of $2.50 per day, the hospital was eager to point out that Protonix had no FDA indications and no dosing information for most commonly treated gastrointestinal conditions. These documents further discourage the use of Proton Pump Inhibitors by stating that Proton Pump Inhibitors interact and interfere with the gastrointestinal absorption of multiple drugs. This adverse information about Proton Pump Inhibitors was provided to the Committee at a time when it appears there was no deep discounting of either Prevacid or Protonix (***Exhibit 20***, attached hereto and made a part hereof).

63. On August 8, 2000, Dr. LaCorte sent a letter with 10 exhibits to the Louisiana State

Board of Medical Examiners (***Exhibit 21***, attached hereto and made a part hereof), expressing his concerns about Automatic Substitution of Drugs on Hospitalized Patients and requesting an advisory opinion with respect thereto. Some of Dr. LaCorte's concerns were the increased cost to the patients and payers, the lack of relevant information given to members of the P&T Committees, conflicts of interest of the members of medical staff committees, and the lack of patient knowledge and consent.

64. On September 12, 2000, Dr. LaCorte received a response to his request for an advisory opinion from the Louisiana State Board of Medical Examiners (hereinnafter sometimes referred to as "LSBME") , the licensing Board appointed by the Governor and charged to protect the public health, safety, and welfare of the citizens of Louisiana. The LSBME concluded: "It is the Board's opinion, then, that automatic substitution of medication, without the prescribing physician's patient-specific authorization, is *per se* inappropriate and unlawful....A pharmacist who initiates a medication substitution would, in fact, be making assessments of a patient's symptoms and critical determinations as to whether a medication, other than that prescribed by the treating physician will provide the therapeutic benefits intended without any attendant adverse [e]ffects or risks. By definition, such services go well beyond the scope of authority provided to pharmacists by law." (***Exhibit 22***, attached hereto and made a part hereof). The terms of Wyeth's Protonix Performance Agreement necessarily induced hospitals to engage in therapeutic interchange of other PPI's for Protonix, a fact of which Wyeth was aware. Nevertheless, Wyeth failed to make disclosures as to such therapeutic interchange to the state medical licensing boards and seek compliance with the state medical nursing and pharmacy practice acts.

65. Since Dr. LaCorte was a member of the East Jefferson Hospital Pharmacy and Therapeutics Committee, he reported the adverse effects, the incorrect dosing information, and the opinion of the Louisiana State Board of Medical Examiners to the Committee Chairman, Dr. Jesse Penico, stating that automatic substitution was *per se* inappropriate and unlawful. Dr. Penico ordered it stopped in his correspondence to the Pharmacist, dated September 14, 2000: "LAST BUT NOT LEAST, SWITCHING PATIENTS FROM LOW-COST GENERIC AND LOWER-COST PROPRIETARY AGENT TO NAME BRAND WHICH WILL BE CONTINUED UPON DISCHARGE IS AT GREATER COST TO THE COMMUNITY AND THE PATIENT, IS NOT SERVING OUR MISSION AS A COMMUNITY HOSPITAL. WE SHOULD STOP AUTOMATIC SUBSTITUTES AT ONCE AND SHOULD CALL EACH PHYSICIAN FOR EACH PATIENT PRIOR TO CHANGING ANY DOCTOR'S ORDER." Instead of stopping the practice, the chief Pharmacist cancelled the Pharmacy & Therapeutics (P&T) Committee meeting, as set forth more fully below. (***Exhibit 23***, attached hereto and made a part hereof).

66. On September 15, 2000, Malcolm P. Schuler, Pharm.D., Clinical Manager of East Jefferson General Hospital Pharmacy Department, sent a memorandum to all nursing and all pharmacy Personnel: RE: PROTON PUMP INHIBITOR THERAPEUTIC INTERCHANGE REVISION. "At it's [sic] July 18, 2000 meeting, the Pharmacy and Therapeutics Committee replaced lansopropole (Prevacid) with pantoprozole (Protonix) as East Jefferson Hospital's Proton Pump Inhibitor (PPI) of choice. It will result in a 25% reduction in PPI expenditures. When orders are written for all other PPI's, it will result in automatic therapeutic substitution to Protonix. The

change will go in effect September 26, 2000." (***Exhibit 24***, attached hereto and made a part hereof).

67. Although the full East Jefferson P&T Committee voted to stop "Therapeutic Interchange" at a subsequent meeting, this was not accurately reflected in the minutes. "Therapeutic Interchange" did not stop, and the pharmacist cancelled the meeting in a communication which he falsely represented as being authored by Dr. Penico. On December 19, 2000, Dr Penico wrote a letter to the East Jefferson Hospital Medical Director, with copies to the Chief of Staff and members of the Executive Committee protesting these actions (***Exhibit 25***, attached hereto and made a part hereof).

68. On December 22, 2000, Dr. Penico wrote a letter to Dr. LaCorte summarizing a meeting he had had with hospital administration concerning these issues. "I believe their inaction is now more than inertia. It is a belief on their part, in my opinion, that they and not the medical staff are and should be in control of medical judgement matters, with apparently the hospital bottom line as the overriding concern." (***Exhibit 26***, attached hereto and made a part hereof).

69. Finally, on December 26, 2000, Dr. Penico wrote a letter of resignation. "Since the P&T committee was cancelled without my knowledge or agreement, yet with my signature attached, and the minutes of meeting either altered or apparently possibly purposely misinterpreted I believe the P&T committee is not acting as a Medical Staff Committee. Therefore, I tender my resignation as P&T committee Chairman." (***Exhibit 27***, attached hereto and made a part hereof).

70. On February 12, 2001, the Louisiana State Board of Medical Examiners wrote to the East Jefferson Hospital attorney to give him the result of the reconsideration hearing, which the

hospital had requested. "With apologies for the delay in responding, the Board asked me to . . . advise you that for reasons more fully enumerated in previous communication to Dr. Ellis, it has concluded to reaffirm its prior advice [that automatic substitution requires a physician's patient-specific authorization; otherwise, that therapeutic interchange is per se illegal]." (***Exhibit 28,*** attached hereto and made a part hereof).

71. On March 20, 2001, the East Jefferson Pharmacy and Therapeutics Committee voted again to stop "Therapeutic Interchange." Dr. LaCorte argued to defer the decision to use Protonix as their formulary Proton Pump Inhibitor to the gastroenterology department, since Protonix had only one of the eight FDA indications found with PPI's. If gastroenterologists were to order it for off label use, that would have been acceptable, but Dr. LaCorte voiced his objection to a drug being automatically "Therapeutically Interchanged" (***Exhibit 29***, attached hereto and made a part hereof). At that time, Dr. LaCorte was unaware that Wyeth was paying gastroenterologists $750-1,000 an hour to present Wyeth's slides marketing Protonix for off-label uses to doctors at restaurants.

72. On March 25, 2001–despite all of the aforementioned actions to stop Therapeutic Interchange (including two letters from the Louisiana State Board of Medical Examiners, stating that Therapeutic Interchange is illegal)–when a nurse attempted to follow Dr. LaCorte's order to administer Prevacid, the computer on the 7 East nurses' station used to order medication directed the nurse to use PO Protonix, instead of Prevacid, on one of Dr. LaCorte's patients to treat her gastric ulcers, a condition for which Protonix had no FDA indication. However, they were instructed to use Prevacid for patients with N/G (nasogastric) tubes. (***Exhibit 30***, attached hereto and made a part

hereof).

73. On May 1, 2001, a memo entitled "East Jefferson General Hospital Drug Formulary Changes" was posted at the nurses' station. East Jefferson Hospital stopped "Therapeutic Interchange." "Instead of therapeutic interchange, EJGH will utilize a more restrictive formulary....If a physician orders a drug that is not on the approved Formulary, he/she shall be contacted by the pharmacy to be informed of the situation. The pharmacist will ask the prescribing physician if the formulary can be used for that patient." Also, "Pending approval of the GI/Endoscopy Committee, Pantoprazole (Protonix) has been selected as the EJGH formulary agent." (***Exhibit 31***, attached hereto and made a part hereof).

74. In October of 2001, The Committee on Geriatrics and Chronic Disease presented a Resolution against Automatic Substitution/Therapeutic Interchange (Resolution 304) at the annual House of Delegates meeting of the Louisiana State Medical Society, which was consistent with the opinion of the Louisiana State Board of Medical Examiners (***Exhibit 32***, attached hereto and made a part hereof).

75. On October 17, 2001, the Louisiana Hospital Association and the Metropolitan Hospital Association both issued calls to action to their administrator members in opposition to Resolution 304 (***Exhibits 33-34***, attached hereto and made a part hereof): "If you have physicians going to this meeting to oppose this resolution, please contact Clark Cosse ... so we can get an idea of the number of physicians who will speak on behalf of hospitals. Talking points are attached for physicians planning to participate in opposing Resolution 304." Also, the Metropolitan instructs the

hospital administrators: What can you do? *"Request that a physician from your P&T Committee attend the House of Delegates meeting to voice opposition to Resolution 304 and vote against the measure. Please make sure that the physician you select to represent your facility understands the issue and is in support of formularies and therapeutic interchange. The physicians must be a member of the LSMS, and gain delegate voting status through their local parish chapter."*

76. On October 28, 2001, Dr. LaCorte wrote a letter with 13 exhibits to Dr. Janet Woodcock, Director of the Center for Drug Evaluation and Research at the FDA, and expressed a number of safety concerns, including: "The Hospital Pharmacy and Therapeutics Committee often disregard the physician's patient specific order and automatically substitute and prescribe medications which lack FDA indication for the condition being treated." (***Exhibit 35***, attached hereto and made a part hereof).

77. On November 9, 2001, Clark Cosse, a lawyer and Vice President of Legal & Governmental Affairs for the Louisiana Hospital Association issued a Memorandum to his hospital members: "Irrefutably, the LBME laws and rules have NO effect on hospitals or their formularies. LBME's only authority is over doctors, not hospitals. Resolution 304 failed, but in the meantime, the LBME opinion still exists. So efforts to change the LBME's opinion will continue, and if necessary, legislation should be introduced in the 2003 legislative session." (***Exhibit 36***, attached hereto and made a part hereof.)

78. On February 27, 2002, a presentation was made to the Specialty Hospital Long Term Acute Pharmacy and Therapeutics Committee by the PharmaSource Director of Clinical Services,

documenting that if Protonix were interchanged for all other PPI's, Protonix 40 mg. could be obtained for $.16 per pill pursuant to the Protonix Performance Agreement. PharmaSource's parent company was Doublin and Beechwood from Ohio, and the drugs were purchased through NCS. (***Exhibit 37,*** attached hereto and made a part hereof.)

79. On March 21, 2002, Dr. LaCorte filed a Federal False Claims Act Complaint against Wyeth, alleging that Wyeth had not reported to the federal Government the Protonix "best price," pursuant to the Medicaid Rebate Statute, and that Wyeth's scheme of Therapeutic Interchange had resulted in automatic unapproved uses of Protonix for diseases which have not been shown to be safe and effective and which lack FDA indications.

80. Dr. LaCorte received a letter dated July 16, 2002 from the Louisiana Medicaid program, implementing the second phase of the prior authorization program. Like the first phase, phase two had no limitation on the use of Proton Pump Inhibitors. (***Exhibit 38***, attached hereto and made a part hereof.)

81. In July of 2002, Dr. LaCorte received Protonix promotional material which stated that Protonix is "A logical choice for treating erosive GERD in the elderly. Effective long-term * control of erosive GERD." Contrary to Wyeth's representation, (***Exhibit 39***, attached hereto and made a part hereof),[4] "*Protonix is indicated for the treatment and maintenance of healing of erosive esophagitis with associated GERD symptoms"–not for the treatment of erosive GERD.

82. In August 2002, Pharmerica Nursing Home pharmacy sent a "Dear Health Care

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[4] ***This promotion represents an off-label indication for Protonix.***

Professional" letter, stating: "Based on the P&T Committee's evaluation and further analysis of cost data, Pharmerica selects the most appropriate products for elderly residents to include within the Select Formulary. For elderly residents requiring proton pump inhibitor (PPI) therapy, Protonix (pantoprazole sodium) Delayed –Release Tablets has been granted preferred status on PharMerica's Select Formulary. Protonix is the logical choice for treating erosive GERD in the elderly." The letter goes on to state: "Prescribing in compliance with the formulary is an appropriate way to treat residents while containing costs. This will also minimize the number of calls and interventions from nursing and pharmacy to prescriptions to change prescriptions to formulary-preferred drugs." Thus, the P&T Committee had chosen a drug that lacked most long-term FDA indications in patients in long term care facilities, based on the terms of the Protonix Performance Agreement (***Exhibit 40***, attached hereto and made a part hereof.)[5]

83. In October 2002, after Dr. LaCorte and other physicians learned how to deal with the Parliamentary move of the hospital associations and their agent doctors, the Louisiana State Medical Society passed a motion consistent with the Louisiana State Board of Medical Examiners "that the Louisiana delegation introduce a resolution at the AMA House of delegates to modify existing policy to include prior patient specific authorization by the treating physician and not allow any automatic substitution/interchange of medication." (***Exhibit 42,*** attached hereto and made a part hereof.)

84. On February 11, 2003, Touro Infirmary sent a "Dear Doctors" letter from the

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[5] *Protonix's safety and efficacy for maintenance therapy beyond 16 weeks has not been established. (**Exhibit 41**, attached hereto and made a part hereof).*

pharmacy department indicating that there was a current Protonix shortage and, at the time, they were not substituting Protonix for Prevacid. (***Exhibit 43***, attached hereto and made a part hereof.)

85. On July 31, 2003, a handwritten note was posted on the Four South nurses' station at Memorial Hospital: "IV Protonix is not available in Pharmacy." Dr. LaCorte noted that they ran out over the weekend (***Exhibit 44***, attached hereto and made a part hereof). Dr. LaCorte now believes that they "ran out" because they had not yet signed the market share contract and, rather than pay full price, they did not order any more Protonix; or probably because the PPA's market share requirement for a discounted price was not met and now the hospital had to pay full price. (See Memorial P&T Committee Notes).

86. The minutes of the August 12, 2003 Memorial Pharmacy and Therapeutics Committee reflect a presentation by the new Director of Pharmacy under the heading Formulary Additions "Mr. Hebert presented a summary and comparison for various Proton Pump Inhibitors (PPI's) for consideration. Mr. Hebert noted that Prevacid is currently on the Formulary." (***Exhibit 45***). The Pharmacy presented a table: Costs of PPIs: The pharmacy represented that the cost per unit of Protonix is $0.17. The cost of generic Omeprazole was represented to be $3.09 per unit. This representation drew the attention of Dr. LaCorte, since Brand OTC Prilosec was available to the general public in most drug stores for only $0.40 per unit. The Pharmacy recommendation was to retain Lansoprazole and Pantoprazole on formulary. Among the stated reasons was that "all Proton Pump Inhibitors appear to be therapeutically equivalent." Additionally, "We currently pay $4.29 per vial for Pantoprazole. In order to prevent an increase to $25.00 per vial, Protonix must be >40% of

the PPI market." "Pharmacy Requests automatic therapeutic substitution as follows: Protonix 40 mg shall be substituted for all other PPI dosages. If the patient has an NG [nasogastric] tube or is a pediatric patient, Pharmacy will substitute Lansoprazole." He wished to add Protonix, and Dr. LaCorte wished to add Prilosec to the formulary, since Prilosec was available as a generic and would save patients money upon discharge. The minutes reflect that both Protonix and Prilosec were added to the formulary, but do not indicate or authorize that Protonix will be substituted for all of the other Proton Pump Inhibitors.

87. There is a misstatement within the aforementioned minutes to the effect that Protonix has an FDA indication for symptomatic gastroesophageal reflux disease. The footnote cites a publication in support of this proposition: Leonard, Mandy, Esomeprazole (Nexium): A New Proton Pump Inhibitor, Pharmacotherapy Update, Vol. IV, No. IV July/August 2001.

88. Although Prilosec has all relevant FDA indications, is available in a relatively inexpensive generic, and was placed on the Memorial Formulary, Dr. LaCorte documented multiple instances of the Memorial Hospital pharmacists switching patients from generic Omeprazole to brand Protonix. However, Protonix is more expensive and has not been proven safe and effective for most of the clinical conditions of the hospitalized GI patients who often need their pills crushed.

89. On September 8, 2003, Mariner Health Care sent a letter: "Dear Mariner Medical Director and Mariner Physicians: ... Mariner Health Care has partnered with Omnicare, Inc....Mariner Health Care has developed and will endorse the Mariner Health Care Therapeutic Exchange Program. This program will promote medication management, which is therapeutically

superior or equivalent to alternatives, while providing cost savings." (***Exhibit 46***, attached hereto and made a part hereof). This statement is consistent with off-label promotion, as Protonix lacked all the indications for which Prevacid, Aciphex, Nexium, and Prilosec provided treatment. Specifically, Protonix lacks proven efficacy and safety necessary to provide long term treatment for most of the conditions affecting nursing home residents and patients. Additionally, it is significantly more expensive than generic Omeprazole, which the residents should have been allowed to buy at any pharmacy and use in the nursing homes.

B. <u>The Effect of Therapeutic Interchange on Patients</u>

90. On September 12, 2003, Dr. LaCorte received the current listing of drugs on the Medicaid Prior Authorization (PA) Process' Preferred Drug List. The three Proton Pump Inhibitors preferred for Medicaid patients were Prevacid, Omeprezole, and Protonix (***Exhibit 47***, attached hereto and made a part hereof.) This preference was confirmed by Dr. LaCorte's conversation with a pharmacist employed by a small independent pharmacy (***Exhibit 48,*** attached hereto and made a part hereof).

91. Over an extended period of time, Dr. LaCorte noticed that a number of his patients were switched from his prescribed Prilosec or Prevacid to Protonix, both without his approval and without a clear FDA indication for the condition(s) for which they were being administered a different PPI. At least one patient who was switched to Protonix developed upper GI bleeding, due to the fact that Protonix was not approved or indicated for GI bleeding.

92. Although most of the patients were on a PPI prior to their arrival to the hospital or

were prescribed a PPI upon their admission, specifically to prevent GI bleeding, they were switched to Protonix tablets or I.V. upon their admission, despite the contraindication to and dangers associated with switching them from the medication that they were already receiving, and despite the egregious fact that Protonix clearly lacked any FDA indication for prophylaxis against GI bleeding.

93. Moreover, some of Dr. LaCorte's patients were on feeding tubes (PEG tubes). As a result of Wyeth's financial inducements to hospitals, hospitals would crush Protonix tablets and insert them into the feeding tubes of patients, although crushing the Protonix tablets rendered them ineffective. Disastrously, when Dr. LaCorte objected to the crushing of tablets, the patients were instead placed on Protonix I.V., which was not indicated for the prevention of GI bleeding, as Dr. LaCorte wanted to achieve for his patients on feeding tubes. Specifically, Dr. LaCorte knows of Patient AR, who was admitted to Memorial Medical Center, Baptist Campus (hereinafter sometimes referred to as "Memorial Medical Center"), in New Orleans, Louisiana on November 17, 2003. Patient AR was to receive Prilosec 20 mg through his feeding tube. Unfortunately, the nurses were crushing the Protonix, so that the hospital could achieve its market share, and administering the crushed tablets through the patients' feeding tubes. As a result of receiving an ineffective PPI due to the crushing, Patient AR developed a bleeding ulcer, which extended his stay until December 17, 2003. This clearly caused additional loss to his Medicare and Blue Cross Blue Shield Carriers.

94. The following are additional examples of some of Dr. LaCorte's numerous patients:

a. **Patient EM:** Patient EM was a Medicaid patient who was admitted to

Memorial Medical Center on October 28, 2004. Upon admission and discussion with Dr. LaCorte, the Emergency Room physician continued EM on her Prevacid 30 mg daily that she had already been receiving as an outpatient. The Nursing Home progress note, as well as the Nursing Home Medication Administration Record (MAR), confirmed that EM was already on Prevacid 30 mg daily. Dr. LaCorte twice checked the following box on the Order sheet: "Therapeutic Interchange is NOT authorized." Despite the lack of physician authorization on the Emergency Room Orders, as well as the physician's Orders reflecting the lack of authorization by the checked-off box, Patient EM was switched to Protonix once a day as a substitute for her Lansoparzole (Prevacid CPDR 30 mg daily p.o.), from October 29 through November 1, 2004.

b. **Patient WG:** Patient WG was an elderly patient who was a Louisiana Medicaid beneficiary and nursing home resident. WG was receiving Prevacid 30 mg daily at his nursing home for his gastric reflux. The patient was admitted to the hospital on October 15, 2004, and Dr. LaCorte checked the box: "Therapeutic Interchange is NOT authorized." Despite the specific instructions for no Therapeutic Interchange, WG received Protonix once daily in lieu of the Lansoparzole (Prevacid CPDR 30 mg daily p.o.), on October 16, 17, and 18, 2004.

c. **Patient EG:** Patient EG was a Medicare and Medicaid beneficiary. On October 21, 2004, EG was admitted to Memorial Medical Center, and the admitting Emergency Room physician continued EG on her outpatient Prevacid. Despite specific instructions by the Emergency Room physician that Therapeutic Interchange was not authorized, a Therapeutic Interchange form was placed to an order sheet placed on EG's chart on October 21, 2004, stating:

"Your order for Prevacid 300 [sic] mg daily was therapeutically interchanged with Protonix 40 mg daily, as approved by the Pharmacy & Therapeutics Committee and the Medical Staff Executive Committee."

d. **Patient CH:** Patient CH was admitted to Touro Rehabilitation in New Orleans, Louisiana, on September 1, 2004, for rehabilitation following a stroke. He was a Medicare beneficiary who had been transferred from LifeCare Hospital, where he was receiving Prevacid 30 mg daily and Zantac 150 mg qhs (at bedtime), which was reordered by the new primary care physician, who was also a Touro Rehab physician. His previous medications had been ordered by Dr. LaCorte as his internal medicine and geriatrics specialist. Despite the rehabilitation specialist ordering the continuation of his medication, and Dr. LaCorte's repeat of the same orders, CH was switched to Pepcid and Protonix. The MAR, dated September 20, 2004, documented this change in medications as per formulary substitution. The GI consultant, Dr. Herbert Mayer, documented that CH had AV malformation and gastritis, conditions for which Protonix clearly lacked an FDA indication.

e. **Patient LD:** Patient LD was a Medicare and Medicaid beneficiary, with Medicaid paying for her medications. LD was admitted to Memorial Medical Center on August 27, 2004. The nursing home progress note of August 3, 2004 indicates that she was stabilized on Prevacid. The MAR indicates that she was under the care of Dr. Eduardo Rodriguez, who had prescribed Prevacid 30 mg, 1 capsule per day. Also, upon her admission to Memorial Medical Center, the Emergency Room physician ordered Prevacid 30 mg. Despite her physicians' clear

orders, a Therapeutic Interchange Form was placed on LD's chart on August 27, 2004, stating: "Your order for Prevacid 30 mg daily was therapeutically interchanged with Protonix 40 mg daily, as approved by the Pharmacy & Therapeutics Committee and the Medical Executive Committee." The Therapeutic Interchange Form was stuck to physician orders for medicines and treatments that have "Geriatric Approved Therapeutic Substitution Authorized Unless Noted in Orders." However, in the case of LD, the box was checked stating that Therapeutic Interchange is not authorized. Yet, Patient LD received multiple doses of Protonix.

f. **Patient MP:** Patient MP was a Medicare and Medicaid beneficiary admitted to Memorial Medical Center on November 2, 2004. MP was receiving Prevacid 30 mg daily, as reflected in her nursing home progress notes. MP had a documented tissue biopsy, confirming the diagnosis of intense chronic antrogastritis. The Emergency Room physician's admission orders prescribed that she continue on her nursing home medication, Prevacid 30 mg once a day. Once again, a pharmacist placed a Therapeutic Interchange Form on MP's chart, notifying the admitting physician: "Your order for Prevacid 30 mg daily was therapeutically interchanged with Protonix 40 mg daily, as approved by the Pharmacy & Therapeutics Committee and the Medical Executive Committee." The hospital pharmacist instituted the therapeutic interchange with Protonix, despite the clear order from the Emergency Room physician, and despite the fact that she had two different forms of order sheets from the nursing units, one of which offered a box to be checked, indicating that Therapeutic Interchange is not authorized. The following day, Dr. LaCorte also checked the box that Therapeutic Interchange is not authorized. Dr. LaCorte also checked the same box on two